

Substitute for form 1449B/PTO

**SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT
IN AN APPLICATION
LISTING OF REFERENCES**

June 11, 2008

Use several sheets if necessary)

ATTORNEY DOCKET NO.
3506.1021-000

APPLICATION NO.
10/519,594

FIRST NAMED INVENTOR
David Cavalla

FILING DATE
December 28, 2004

EXAMINER
Layla Soroush

CONFIRMATION NO.
2624

GROUP
1617



U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
/LS/	U3	4,845,092	07-04-1989	Sanger <i>et al.</i>
	U4	4,939,136	07-03-1990	Haack <i>et al.</i>
	U5	5,225,407	07-06-1993	Oakley <i>et al.</i>
	U6	5,352,685	10-04-1994	Maruyama <i>et al.</i>
	U7	5,434,174	07-18-1995	Gidda <i>et al.</i>
	U8	5,438,068	08-01-1995	Eeckhout <i>et al.</i>
	U9	5,470,868	11-28-1995	Young
	U10	5,530,008	06-25-1996	Azcona <i>et al.</i>
	U11	5,576,317	11-19-1996	Gonsalves
	U12	5,663,343	09-02-1997	van der Meij <i>et al.</i>
	U13	5,708,033	01-13-1998	Kelley <i>et al.</i>
	U14	5,945,415	08-31-1999	Kato <i>et al.</i>
	U15	5,962,494	10-05-1999	Young
	U16	5,977,127	11-02-1999	Bonnacker <i>et al.</i>
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	U18	5,985,866	11-16-1999	Müller <i>et al.</i>
	U19	5,990,159	11-23-1999	Meulemans <i>et al.</i>
	U20	6,054,461	04-25-2000	Fairbanks <i>et al.</i>
	U21	6,117,879	09-12-2000	Fairbanks <i>et al.</i>
	U22	6,156,771	12-05-2000	Rubin <i>et al.</i>

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/LS/	U23	6,194,382	02-27-2001	Crain, <i>et al.</i>
	U24	6,211,171 B1	04-03-2001	Sawynok <i>et al.</i>
	U25	6,235,745 B1	05-22-2001	Megens
	U26	2001/0020025 A1	09-06-2001	Megens
	U27	6,300,336 B1	10-09-2001	Eeckhout <i>et al.</i>
	U28	2001/0044450 A1	11-22-2001	Mangel <i>et al.</i>
	U29	2001/0056110 A1	12-27-2001	Faerber <i>et al.</i>
	U30	2002/0002197 A1	01-03-2002	Mueller <i>et al.</i>
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	U39	6,440,453 B1	08-27-2002	Fischer <i>et al.</i>
	U40	6,441,038 B1	08-27-2002	Loder <i>et al.</i>
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	U42	6,465,458 B1	10-15-2002	Wong <i>et al.</i>

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/LS/	U43	7,220,748	05-22-2007	Cavalla <i>et al.</i>
	U44	6,476,078 B2	11-05-2002	Jerussi <i>et al.</i>
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	U46	6,558,708 B1	05-06-2003	Lin
	U47	6,566,369 B2	05-20-2003	Cautreels <i>et al.</i>
	U48	2003/0125349 A1	07-03-2003	Cautreels <i>et al.</i>
	U49	6,593,336 B2	07-15-2003	Mangel <i>et al.</i>
	U50	2003/0158221 A1	08-21-2003	Zhang <i>et al.</i>
	U51	2003/0203055 A1	10-30-2003	Rao <i>et al.</i>
	U52	2006/0217391 A1	09-28-2006	Landau
	U53	2004/0048874	03-11-2004	Bardsley
	U54	2004/0147509 A1	07-29-2004	Landau
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	U61	2004/0259862 A1	12-23-2004	Landau
V	U62	2005/0032780 A1	02-10-2005	Landau

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/LS/	U63	2005/0192270 A1	09-01-2005	Landau
	U64	2005/0239792	10-27-2005	Cavalla <i>et al.</i>
	U65	7,094,786	08-22-2006	Landau
	U66	2006/0167005	07-27-2006	Cavalla <i>et al.</i>

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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES	NO
/LS/	F3	WO 88/04173	06-16-1988	Serotonin Industries of Charleston		
	F4	EP 0 297 651 B1	11-03-1993	Duphar International Research B.V		
	F5	WO 94/01095	01-20-1994	Smith-Kline Beecham PLC		
	F6	WO 96/11009	04-18-1996	Loder, Cari		
	F7	WO 98/01157	01-15-1998	The WWK Trust		
	F8	WO 98/08520	03-05-1998	Scotia Holdings PLC		
	F9	WO 98/09623	03-12-1998	Scotia Holdings PLC		
	F10	WO 98/50037	11-12-1998	Mitsubishi Chemical Corporation		X
	F11	WO 00/48581 A3	08-24-2000	Novartis AG		
	F12	WO 00/48597	08-24-2000	Novartis AG		
	F13	WO 00/51583	09-08-2000	Sepracor, Inc.		
	F14	WO 00/51584	09-08-2000	Sepracor, Inc.		
	F15	WO 01/26623 A3/A2	04-19-2001	Laxdale Limited		
	F16	WO 02/07713 A2	01-31-2002	Solvay Pharmaceuticals GMBH		X
	F17	EP 1 230 921 A1	08-14-2002	Pfizer Products, Inc.		
	F18	WO 02/083926 A3/A2	10-24-2002	Cedars-Sinai Medical Center		
	F19	WO 02/094249 A1	11-28-2002	Arachnova Therapeutics Ltd.		
	F20	WO 03/061657 A1	07-31-2003	Aryx Therapeutics		
	F21	WO 03/063873 A1	08-07-2003	Arachnova Therapeutics, Ltd.		

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/LS/	F22	WO 03/077897 A1	09-25-2003	Cypress Bioscience, Inc.		
	F23	WO 2004/004734 A1	01-15-2004	Arachnova Therapeutics Ltd.		
	F24	WO 2004/019948 A1	03-11-2004	Arachnova Therapeutics, Ltd.		
	F25	WO 2004/058353 A3/A2	07-15-2004	Amedis Pharmaceuticals, LTD.		
	F26	WO 2004/062623 A2	07-29-2004	Dynogen Pharmaceuticals, Inc.		
	F27	WO 2004/062624 A3/A2	07-29-2004	Dynogen Pharmaceuticals, Inc.		
	F28	EP 0150469	06-15-1988	Mitsubishi Chemical Industries Limited		

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		OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
/LS/	R3	"How to Avoid a Health Insurance Claim Denial- and What to do When You Can't," [Retrieved on 03-15-2005]. Retrieved from the Internet <URL:http://info.insure.com/health/claimdenial.html>, pp 1-4.
/LS/	R4	"Irritable Bowel Syndrome at a Glance - Nosology, Epidemiology, and Pathophysiology (Monograph I), December 2002 [Retrieved on 2002-12-12]. Retrieved from the Internet <URL:http://fdhn.org/html/education/gi/ibs_nosology.htm>, pp. 1-2.
/LS/	R5	"Dynogen Pharmaceuticals, Inc. Enters Into Agreement With Mitsubishi Pharma For Irritable Bowel Syndrome Compound," Dynogen Pharmaceuticals, Inc. Press Release, pp. 1-2 [online], (December 22, 2003). Retrieved from the Internet <URL: www.dynogen.com>.
/LS/	R6	Angel, I., <i>et al.</i> "Litoxetine: A Selective 5-HT Uptake Inhibitor with Concomitant 5-HT ₃ Receptor Antagonist and Antiemetic Properties," <i>Eur. J. Pharmacol.</i> , 232(2/3):139-145 (1993).
/LS/	R7	Béïque, J.C., <i>et al.</i> , "Affinities of Venlafaxine and Various Reuptake Inhibitors for the Serotonin and Norepinephrine Transporters," <i>Eur. J. Pharmacol.</i> , 349(1):129-132 (1998).
/LS/	R8	Burns, M.J., "The Pharmacology and Toxicology of Reboxetine," <i>Int. J. Med. Toxicol.</i> 3(4):26 1-7 (2000).
/LS/	R9	Bymaster, F.P., <i>et al.</i> "Comparative Affinity of Duloxetine and Venlafaxine for Serotonin and Norepinephrine Transporters <i>in vitro</i> and <i>in vivo</i> , Human Serotonin Receptor Subtypes, and Other Neuronal Receptors," <i>Neuropsychopharmacology</i> , 25(6):871-880 (2001).
/LS/	R10	Camilleri, M., "Serotonergic Drugs: Emerging Therapies for Irritable Bowel Syndrome," <i>In Irritable Bowel Syndrome a Clinician's Guide</i> , M. Camilleri and R. C. Spiller, eds., Chapt. 19; pp 1-10 (2002).
/LS/	R11	Camilleri, M., "Serotonergic Modulation of Visceral Sensation: Lower Gut," <i>Gut</i> 51(Supp. 1):i81-i86 (2002).
/LS/	R12	Center for Drug Evaluation and Research Application Number: 020623; Pharmacology Reviews; July 5, 1996, pp. 1-40.
/LS/	R13	Database CIN 2004-01-05, "Life Sciences in Brief," [online], January 5, 2004 (retrieved online January 31, 2006). Retrieved from: STN Database, Accession No. 33(3):1518T.
/LS/	R14	Database IMSDRUGNEWS, R&D Focus Drug News, "DDP 225 Dynogen, Mitsubishi Pharma Licensing Agreement," [online], January 12, 2004. Retrieved from: STN Database, Accession No. 2004:188.

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/LS/	R15	Depoortere, I., et al., "Dose-Dependent Effects of Recombinant Human Interleukin-11 on Contractile Properties in Rabbit 2,4,6-Trinitrobenzene Sulfonic Acid Colitis," <i>J. Pharmacol. Exp. Ther.</i> , 294(3): 983-990 (2000).
/LS/	R16	Drossman, D.A., et al., "Irritable Bowel Syndrome: A Technical Review for Practice Guideline Development," <i>Gastroenterology</i> , 112: 2120-2137 (1997).
/LS/	R17	Eguchi, J., et al., "Pharmacological Profile of the Novel Antidepressant 4-(2-Fluorophenyl)-6-methyl-2-(1-piperazinyl)thieno-[2,3-d]pyrimidine Monohydrate Hydrochloride," <i>Arzneim. - Forsch./Drug Res.</i> , 47(12): 1337-1347 (1997).
/LS/	R18	Fairweather, D.B., et al., "The Psychomotor and Cognitive Effects of Litoxetine in Young and Middle Aged Volunteers," <i>Br. J. Clin. Pharmacol.</i> , 40(2):119-125 (1995).
/LS/	R19	Gebhart, G.F., "Pathobiology of Visceral Pain: Molecular Mechanisms and Therapeutic Implications IV. Visceral Afferent Contributions to the Pathobiology of Visceral Pain," <i>Am. J. Physiol. Gastrointest. Liver Physiol.</i> 278:G834-G838 (2000).
/LS/	R20	Goldberg, P.A., et al., "Modification of Visceral Sensitivity and Pain in Irritable Bowel Syndrome by 5-HT ₃ Antagonism (Ondansetron)," <i>Digestion</i> , 57(6):478-483 (1996).
/LS/	R21	Greenbaum, D.S., et al., "Effects of Desipramine on Irritable Bowel Syndrome Compared with Atropine and Placebo," <i>Digestive Diseases and Sciences</i> , 32(3): 257-266 (1987).
/LS/	R22	Ishigooka, Jr., et al., "Serotonin-Noradrenaline Reuptake Inhibitors(SNRIs)," <i>Nippon Rinsho</i> , 59, pp. 1523-9, (2001) - Abstract Only.
/LS/	R23	Ito, C., et al., "Effect of GK-128 [2-[(2-Methylimidazol-1-yl)methyl]- benzo[f]thiochromen-1-one Monohydrochloride Hemihydrate], a Selective 5-Hydroxytryptamine ₃ Receptor Antagonist, on Colonic Function in Rats," <i>J. Pharmacol. Exp. Ther.</i> , 280(1): 67-72 (1997).
/LS/	R24	Jin, J.G., et al., "Propulsion in Guinea Pig Colon Induced by 5-Hydroxytryptamine (HT) via 5-HT ₁ and 5-HT ₂ Receptors," <i>J. Pharmacol. Exp. Ther.</i> , 288(1): 93-97 (1999).
/LS/	R25	Kozlowski, C.M., et al., "The 5-HT ₃ Receptor Antagonist Alosetron Inhibits the Colorectal Distention Induced Depressor Response and Spinal c-fos Expression in the Anaesthetised Rat," <i>Gut</i> , 46: 474-480 (2000).
/LS/	R26	LOTROXEX - Tablets, Product Information, GlaxoSmithKline, Research Triangle Park, NC, pp. 1-13 (2002).
/LS/	R27	Mertz, H.R., "Irritable Bowel Syndrome," <i>N. Engl. J. Med.</i> 349(22):2136-2146 (2003).

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/LS/	R28	Million, M., <i>et al.</i> , "Susceptibility of Lewis and Fischer Rats to Stress-induced Worsening of TNB-colitis: Protective Role of Brain CRF," <i>Amer. Phys. Soc.</i> , 276 (4 Pt 1): G1027-G1036 (1999).	
/LS/	R29	Morteau, O., <i>et al.</i> , "Influence of 5-HT ₂ Receptor Antagonists in Visceromotor and Nociceptive Responses to Rectal Distension Before and During Experimental Colitis In Rats," <i>Fundam. Clin. Pharmacol.</i> , 8(6):553-562 (1994).	
/LS/	R30	Owens, M. J., <i>et al.</i> , "Neurotransmitter Receptor and Transporter Binding Profile of Antidepressants and their Metabolites," <i>J. Pharmacol. Exp. Ther.</i> , 283(3): 1305-1322 (1997).	
/LS/	R31	Sach, J. A., <i>et al.</i> , "Irritable Bowel Syndrome," <i>Curr. Treat. Options. Gastroenterol.</i> , 5(4): 267-278 (2002).	
/LS/	R32	Schmulson, M. J., "Brain-Gut Interaction in Irritable Bowel Syndrome: New Findings of a Multicomponent Disease Model," <i>IMAJ</i> , 3:104-110 (2001).	
/LS/	R33	Sheikh, M. Y. and Wright, R. A., "Irritable Bowel Syndrome: Current Concepts and Future Prospects," <i>Hospital Physician</i> , pp. 31-38 (1999).	
/LS/	R34	Spiller, R., "Pharmacotherapy: Non-Serotonergic Mechanisms," <i>Gut</i> , 51, Suppl, i87-i90 (2002).	
/LS/	R35	Steadman, C. J., <i>et al.</i> , "Selective 5-Hydroxytryptamine Type 3 Receptor Antagonism With Ondansetron as Treatment for Diarrhea-Predominant Irritable Bowel Syndrome: A Pilot Study," <i>Mayo Clinic Proc.</i> , 67(8): 732-738 (1992).	
/LS/	R36	Thompson, W. G., <i>et al.</i> , "Functional Bowel Disorders and Functional Abdominal Pain," <i>Gut</i> 45(Supp II):1143-1147 (1999).	
/LS/	R37	U.S. Provisional Application No. 60/364,531, filed 03-15-2002, entitled "Methods of Treating Visceral Pain Syndromes," by Rao <i>et al.</i> , priority document for WO 03/077897 A1 and U.S. 2003/0203055 A1.	
/LS/	R38	Venkova, K., <i>et al.</i> , "Peripheral Activity of a New NK ₁ Receptor Antagonist TAK-637 in the Gastrointestinal Tract," <i>J. Pharmacol. Exp. Ther.</i> , 300(3): 1046-1052 (2002).	
/LS/	R39	Wong, E. H. F., <i>et al.</i> , "Reboxetine: A Pharmacologically Potent, Selective, and Specific Norepinephrine Reuptake Inhibitor," <i>Biol. Psychiatry</i> . 47(9): 818-829 (2000).	
/LS/	R40	Wood, J. D., <i>et al.</i> , "Fundamentals of Neurogastroenterology," <i>Gut</i> 45(Supp. II):116-1116 (1999).	
/LS/	R41	Worsley, A. P. and Allawi, J., "A Combined Treatment for Severe Diabetic Neuropathy Symptoms," in <i>Letters, Diabetic Medicine</i> , 15:797-798 (1998).	

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/LS/	R42	Yuan, S.Y., <i>et al.</i> , "Investigation of the Role of 5-HT ₃ and 5-HT ₄ Receptors in Ascending and Descending Reflexes to the Circular Muscle of Guinea-pig Small Intestine," <i>Br. J. Pharmacol.</i> , 112(4): 1095-1100 (1994).

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